Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12486

0 - FRONT

COMPLAINT/INJURY REPORT

124846

1. COMPLAINT NUMBER: DEN-3841

2. DATE OF COMPLAINT (MONTH/DAY/YEAR): 07/07/97

3. FORM OF COMPLAINT
(1) [X] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
(1) [X] CONSUMER
(2) [ ] GOVERNMENT
(3) [ ] TRADE SOURCE
(4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINT IDENTIFICATION
a. NAME AND ADDRESS (Include Zip Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY: Complaintant making complaint on behalf of his wife, alleging his wife suffered psychological injury as a result of taking product block 8. See attached memorandum for details.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [X] NO
(2) [ ] YES
(Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES
(If "yes" complete Items a through d)

a. EIB (HFC-161) NOTIFIED
(1) [X] NO
(2) [ ] YES
DATE: ^

b. TYPE SYMPTOMS — ONSET (HR)
1. [ ] VOMITING ^
2. [ ] NAUSEA ^
3. [ ] DIARRHEA ^
4. [ ] FEVER ^
5. [ ] SKIN/EYE IRR. ^
6. [ ] HEADACHE ^
7. [X] OTHER ^
"Craziness"

c. ATTENDING HEALTH PROFESSIONAL
(1) [ ] NO (2) [X] YES
(If "yes" give name and address, and phone number)
see attached memo

c. HOSPITALIZATION REQUIRED
(1) [ ] NO (2) [X] YES
(If "yes" give name and address, and phone number)
see attached memo

8. PRODUCT AND LABELING
a. BRAND NAME: E'Ola
b. PRODUCT NAME: (two) Liqui Thin and Amp Pro II
c. SIZE AND PACKAGE TYPE: each product 1 fl. oz.
d. NAME AND LOCATION OF STORE WHERE PURCHASED: Obtained from complaintant's wife's brother; complaintant did not want to reveal brother-in-law's name
e. PACKAGE CODE/SERIAL NUMBER/ETC.: See attached memo
EXP/USE BY DATE:
f. DATE PURCHASED: June, 1997
g. PRODUCT USED (If "yes" enter date)
(1) [ ] NO (2) [X] YES:
h. AMT REMAINING: see memo

MANUFACTURER/ DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: DEN-DO (8)
b. C.F. NO.: 1722358
c. NAME AND LOCATION OF FIRM (Include Zip Code):
E'Ola Products
945 North 1300 West
St. George, UT 84790
d. IMPORT PRODUCT
(1) [X] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX
(2) DESCRIPTION: Reaction

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) [X] IMMEDIATE FOLLOW-UP
(2) [ ] F/U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE/LOCAL AGENCY (Closes File)
(6) [ ] REFERRED TO OTHER FDA ^ DIST.

11. PRODUCT CODE
54FCL09 / 54FCL99

12. INFORMATION COPIES TO:
[ ] HFB-100 [ ] HFZ-343
[ ] HFD-730 [ ] HFC-161
[ ] HFV-236 [ ] ^

REMARKS: see attached memo

Attachment #1.2
E'Ola Products (DEN-3841)
Saint George, UT 84790
MEMO, 8/8/97
James E. Moore II

NAME AND TITLE: Kirk D. Sooter, Supervisory Investigator, DEN-DO / SLC-RP

DATE: 07/09/97

FORM FDA 2516 (1/90)

Circle Appropriate Copy: White copy (Original) Pink Copy Orange Copy Green Copy Yellow Copy

DEPARTMENT OF HEALTH & HUMAN SERVICES

PHS/FOOD AND DRUG ADMINISTRATION
SOUTHWEST REGION/DENVER DISTRICT
P.O. BOX 25087, DENVER, CO 80225

Memorandum

Date: July 9, 1997

From: Kirk D. Sooter, Supervisory Investigator, [redacted] Resident Post

Subject: Complaint DEN-3841

To: Richard I. Aleman, Field Activities Branch Director
Russell W. Gripp, Compliance Officer
Don L. Bean, Consumer Complaint Coordinator

This memorandum serves to further explain entries and allegations made by Mr. [redacted], complainant of DEN-3841.

Mr. [redacted] phoned the [redacted] Resident Post on July 3, 1997 and left a message to return his call. I phoned Mr. [redacted] on July 7 and took his complaint. He alleges that his wife began taking two concomitant dietary supplements, Liqui Thin and Amp II Pro, two weeks ago. Both products are manufactured by E'Ola Products of St. George, UT. Mr. [redacted] stated his wife began taking the products on a Saturday and, by the following Monday, "had gone completely crazy." Mr. [redacted] described his wife's craziness as being unable to listen to reason, being argumentative, making irrational statements, demented or delusional behavior (specifically, his wife wanted to go to work at 3:00 AM when her normal report time is 8:00 AM; further, she wanted to walk to work, which is several miles from her residence), and ignorance or forgetfulness of her existing health situation, including lower back pain resulting from an injury. Mrs. [redacted] is 47 years of age. Mr. [redacted] insists that his wife followed the dosage instructions on both products during the short time she was taking the supplements.

Endorsement

Attachment #1.3
E'Ola Products (DEN-3841)
Saint George, UT 84790
MEMO, 8/8/97
James E. Moore II

Injury resulted to Mrs. [redacted] when, on Monday, June 23, Mr. [redacted] was taking her to work in their truck. About a few blocks from Mrs. [redacted] employer, Mrs. [redacted] stated she wanted out of the truck and would walk. Mr. [redacted] said no. Mrs. [redacted] opened the door of the truck and jumped out while the truck was in motion, doing about 40 miles per hour. Mrs. [redacted] sustained a concussion and contusions and was taken to the [redacted] She was treated and released that day. Mr. [redacted] consulted the attending physician (neurologist), Dr. [redacted] Dr. [redacted] advised Mr. [redacted] to discontinue his wife's use of the dietary supplements and she has not resumed their [redacted] consumption since that date.

Mr. [redacted] also consulted Dr [redacted] attending physician, who had treated Mrs. [redacted] for depression approximately two years ago. Dr. [redacted] made the same recommendation to Mr. [redacted] as Dr. [redacted] Mr. [redacted] stated his wife has been off of Prozac for over a year and is not classified as depressive.

Mr. [redacted] was asked whether his wife was taking any other medications. He responded Restrogen, Primarin, and a prescription stool softener Mr [redacted] could not remember its name.

On the same date, I instructed Consumer Safety Technician John A. Frederick to collect both products from Mr. [redacted] which he did. The samples were identified as 97-452-941 (Liqua Thin) and 97-452-942 (Amp II Pro), and submitted to Denver District on July 8, 1997.

Kirk D. Sooter, Supervisory Investigator
Denver District / [redacted] Resident Post

Attachment #1.4
E'Ola Products (DEN-3841)
Saint George, UT 84790
MEMO, 8/8/97
James E. Moore II

To: RAB - FYI review & let's discuss. KRA 8/12/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

PHS/FOOD AND DRUG ADMINISTRATION
SOUTHWEST REGION/DENVER DISTRICT
P.O. BOX 25087, DENVER, CO 80225

Memorandum

TO: Gary C. Dean, DD, DEN-DO, SWR
Don L. Bean, Consumer Complaint Coordinator
Regina Barrell, CO, DEN-DO, SWR

FROM: James E. Moore II, CSO, DEN-DO, SLC-RP

DATE: August 8, 1997

SUBJECT: E'Ola Complaint Investigation (DEN-3841)

Responsible Firm:
EOLA PRODUCTS
945 North 1300 West
Saint George, UT 84790
CFN: 1722358

PRODUCTS:
Liqua Thin 1 & Amp II Pro

The Denver District [redacted] Resident Post received a complaint (DEN-3841), July 3, 1997, from a Mr. [redacted] concerning an adverse reaction to the dietary supplement E'Ola, Liqua Thin 1 and Amp II Pro. These two products, when used in a tandem, are supposed to help a person lose weight. Mr. [redacted] claimed that after his wife started taking these two products she became "crazy" and was ultimately injured when she jumped from a moving vehicle. Both Mr. and Ms. [redacted] claim that she jumped from the moving truck due to her confusion, caused by the E'Ola products. Ms. [redacted] sought medical attention first from the emergency room at [redacted] and then from a Neurologist, Dr. [redacted] M.D. Samples of the two products, Liqua Thin 1 & Pro II Amp was collected under C/R's #97-452-941 & #97-452-942 (see attachment #2) by the SLC-RP on 7/7/97. Analysis is pending the outcome of investigation. Due to these two E'Ola products, which contain Ephedra, CFSAN requested a more detailed follow up on this complaint. Assignment was issued Thursday, 7/31/97, and received Friday, 8/1/97 (see attachment #1). The assignment was to interview all physicians involved in the complaint, obtain medical records for Ms. [redacted] and document any correlation between the use of the Ephedra product (E'Ola) and the perceived abnormal behavior exhibited by Ms. [redacted], resulting in injury.

Endorsement:
To: Regina Barrell, CO, DEN-DO

Kirk D. Sooter

Kirk D. Sooter, SCSO
DEN-DO, SLC-RP

97 AUG 22 P3:54

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

On 8/5/97, I met with Mr. & Ms. [redacted] at their place of residence [redacted] Mr. & Ms. [redacted], explained that Ms. [redacted] wanting to lose some weight, so she had her brother-in-law (name unknown), from [redacted] provide her with two bottles of E'Ola Product, Liqua Thin 1 & Amp II Pro. This brother-in-law purchased the product from a trade show in [redacted] The product is manufactured by E'Ola Products, St. George, UT. Ms. [redacted] stated that she took the product Saturday and Sunday, 6/7/97 & 6/8/97. Mr. [redacted] said after she took the supplements she became aggressive, unreasonable, confused, delusional and just plain crazy. Mr [redacted] stated that the real problem began when Ms. [redacted] wanted to walk to work at 3:00 a.m., Monday morning 6/9/97. Ms. [redacted] normally starts work at 8:00 a.m. Mr [redacted] stated he made her come back to the house and told her to discontinue using the E'Ola product. Later in the morning, approximately 6:30 a.m., Mr. [redacted] was taking Ms. [redacted] to work, when an argument ensued. Ms. [redacted] stated she became agitated and jumped out of the vehicle. Ms. [redacted] could offer no reasonablely rational for this type of behavior. She stated she never acts in this manner. Thus, she felt it must be a result of the E'Ola products. It should be noted that Mr. [redacted] stated he did nothing to cause Ms. [redacted] to jump from the vehicle, meaning he did not physical hit or push Ms [redacted] Ms [redacted] stated she then sought medical attention from [redacted] and from a Neurologist, Dr. [redacted], M.D. While at the hospital, Mr. [redacted] stated the [redacted] interviewed them to assure this was not a domestic altercation. According to Ms. [redacted] her primary physician, Dr. [redacted] was never consulted concerning this incident. Both Mr. & Ms [redacted] stated that the emergency room physician and Dr. [redacted] instructed her to discontinue the use of the E'Ola product. Additionally, Mr [redacted] stated Ms. [redacted] did not receive a Psychological exam concerning the incident.

Ms [redacted] was taking three prescription medications when she consumed the E'Ola product. These prescriptions are: Levulic, Premarin and Soma p.r.n. Ms [redacted] stated she has also been on Prozac since November 1992 to help cope with the death of her daughter. Ms. [redacted] stated that she did discontinue the Prozac last year, October 1996. Ms. [redacted] is allergic to Aspirin and Penicillin. Mr [redacted] stated that the E'Ola product contains aspirin in the form of White Willow. He states the white willow is labeled on the bottle.

It should be noted that during the interview both Mr. [redacted] and Ms. [redacted] asked, a couple of times, if there is a possibility of suing the manufacturing company (E'Ola Products). It was explained that FDA does not advise on the matters of consumer litigation.

Before the end of the interview, Ms. [redacted] signed the DHHS, PHS, FDA Authorization for Medical Records Disclosure statement. With this disclosure, medical records were obtained from Dr. [redacted], M.D. (See attachment #3), and from [redacted] (attachment #4).

On 8/5/97, I met with Dr. [redacted] M.D., Neurologist. Dr [redacted] stated he treated Ms. [redacted] twice, 6/12/97 & 6/18/97 for her injuries associated with her 6/9/97 accident. Dr [redacted] stated Ms [redacted] had not been referred to him by another physician. He believed Ms. [redacted] came to him by herself. Dr. [redacted] stated that he only treated Ms. [redacted] for her injuries received in the fall from the moving vehicle during the 6/9/97 accident. He said he did not treat or test for injuries associated with the use of the E'Ola dietary supplement product. Indeed, Dr. [redacted] notes (see attachment #3) indicated Ms. [redacted] mentioned that she had taken the E'Ola product and that she was "not herself" while consuming the product. Dr. [redacted] notes/medical records show no testing or correlation of the injuries associated with the accident and the use of the E'Ola product. Additionally, Dr. [redacted] stated there were probably other mitigating factors associated with the accident that caused the injuries. Factors such as domestic issues. His notes indicate that Mr. & Ms. [redacted] had a "minor altercation" just before the accident. Dr. [redacted] does not believe there were any drug interactions associated with the E'Ola product and the three prescription drugs Ms. [redacted] was taking at the time. Dr. [redacted] has not seen any incidents involving E'Ola or Ephedra and could not say it was harmful. He did say that he advised Ms. [redacted] to discontinue the use of the E'Ola product and never use it again. Dr. [redacted] stated he advised her of this due the process of elimination as to the cause of her "not feeling herself." He stated he did not know enough about this dietary supplement, E'Ola, to know if it was harmful. Thus, he felt this was an additional reason to discontinue the E'Ola product.

In summary, Dr. [redacted] did not make a correlation between the E'Ola product and Ms [redacted] abnormal behavior. Dr [redacted] advised Ms. [redacted] to discontinue the product, based on his process of elimination as to the cause of her not feeling herself and his lack of knowledge of the E'Ola product.

No FDA-463a, Affidavit, was obtained from Dr. [redacted] as he could not link Ms [redacted] abnormal behavior to the two dietary supplements (E'Ola).

On 8/5/97, I went to [redacted] and obtained Ms [redacted] emergency medical records for 6/9/97 (see attachment #4). The emergency room attending physician, for Ms. [redacted] on 6/9/97, was Dr. [redacted] M.D. Dr. [redacted] noted in her reports that all vital statistics were normal, except a slightly elevated blood pressure. Dr. [redacted] notes also indicate that the result of the accident was an "Adverse RXN to Liquifilm" (Liqua Thin 1, See attachment #4). Additionally, Dr. [redacted] notes state that Ms. [redacted] told her the liquifilm was making her real agitated. In Dr. [redacted] disposition she states she told Ms. [redacted] "never to take the Liquifilm again."

On 8/6/97, I visited Dr. [redacted] at the [redacted] emergency room, [redacted] had left [redacted] in July 1997 and began full time work at [redacted] After reviewing Ms [redacted] emergency room medical records, Dr. [redacted] stated that she remembers treating Ms. [redacted] for her injuries related to the accident. She stated that she requested no lab analysis or investigation related to Ms [redacted] use of the E'Ola products. Dr. [redacted] stated that Ms. [redacted] queried her often about the possibility that this dietary supplement (E'Ola) caused her to go crazy and jump out of the truck. Dr. [redacted] stated that this is why she advised Ms. [redacted] to discontinue the Liquifilm (E'Ola) product. Dr. [redacted] went on to say that she meant to report that there was a possibility that Ms [redacted] had a reaction to the Liquifilm, and not definitely a reaction. Dr [redacted] did not believe Ms [redacted] accident was a direct result of taking the E'Ola product. She felt that it may have contributed, along with other factors, to Ms. [redacted] being agitated. Lastly, I asked Dr [redacted] given the prescription medications Ms. [redacted] was taking, could there have been a drug interaction with the E'Ola or Ephedra. Dr. [redacted] did not know enough about the product, but she ventured to say that she did not believe an interaction was possible with the indicated medications.

In summary, Dr [redacted] did not make a correlation between the E'Ola product and Ms. [redacted] abnormal behavior. Dr. [redacted] advised Ms. [redacted] to discontinue the product, based on her process of elimination as to the cause of her not feeling herself.

No FDA-463a, Affidavit, was obtained from Dr. [redacted] as she could not link Ms [redacted] abnormal behavior to the two dietary supplements (E'Ola).

On 8/6/97, I visited th [redacted] Police records' department, [redacted] Case # [redacted] (see attachment #5) was obtained. This document is a record of the police call from [redacted] concerning Ms. [redacted] accident. The report shows an employee of [redacted] calling the police for Ms. [redacted] The employee believes Ms. [redacted] was involved in a domestic altercation with her husband and jumped out of a moving vehicle to ensure her safety. This report was filed on a short form and no other reports exist. Specifically, this short report form does not mention the use of the dietary supplement E'Ola, and/or abnormal behavior associated with its use.

Summary:

Although Mr. & Ms. [redacted] claim the E'Ola product caused Ms [redacted] abnormal behavior there is no medical evidence to support this claim. While both Dr [redacted] M.D., and Dr. [redacted], M.D. acknowledge the two E'Ola products may have contributed to Ms. [redacted] agitation and aggressive behavior, they did not persue or investigate that correlation. The only medical attention provided and documented by Dr [redacted] and Dr. [redacted] was for Ms. [redacted] immediate physical injuries suffered in her jump from the vehicle. Further, there was no

psychological examination requested or performed as a result of Ms. [redacted] jumping from a moving vehicle. Additionally, the [redacted] Police report does not indicate that Ms. [redacted] was acting in an aberrant behavior or that she was using a dietary supplement which could have caused her to jump for the vehicle. Lastly, there appears to be some domestic difficulties between Mr. & Ms. [redacted] that obscures the statements the [redacted] made concerning abnormal behavior and the E'Ola products which caused the irrational jump from the truck.

ATTACHMENTS:

1. DEN-DO Assignment, dated 7/31/97, (Copy of complaint #DEN-3841, dated 7/7/97)
2. Copy of C/R #'s 97-452-941 & 97-452-942, dated 7/7/97
3. Ms. [redacted] Medical Records, dated 6/12/97 & 6/18/97, from Dr. [redacted] M.D.
4. Ms [redacted] Medical Records, dated 6/9/97 from [redacted]
5. Copy of Ms. [redacted] Police report, dated 6/9/97.
6. Copy of the Physician Desk reference on Rx; Soma & Premarin

James E. Moore

James E. Moore II
Consumer Safety Officer
DEN-DO, [redacted]